



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Comments on “Draft Guidance: Pesticides; Pesticide Registrants on Herbicide Resistance Management Labeling, Education, Training, and Stewardship (PRN 2017-2)”; EPA-HQ-OPP-2016-0226 and Other Dockets

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TO: EPA Docket: EPA-HQ-OPP-2016-0226

Product Review Panel Review: May 24, 2017

BACKGROUND

This document responds to the public comments received on the draft Pesticide Registration Notice (PRN) entitled, “*PR Notice 2016-XX. Draft Guidance. EPA’s Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship.*” The draft has been revised based on the comments received and the final PRN, 2017-2: *Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship*, may be found at <https://www.epa.gov/pesticide-registration/pesticide-registration-notice-year>.

In June 2016, the United States Environmental Protection Agency (EPA or the Agency) issued and sought public comments on a draft PRN entitled, “*PR Notice 2016-XX. Draft Guidance. EPA’s Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and*

Stewardship.” At the same time, the Agency released the draft PRN 2016-X, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*, which revised and updated PRN 2001-5. Since then, the EPA has incorporated Herbicide Resistance Management language/requirements into the Proposed Interim Decisions of several herbicides and sought comment related to specific chemicals.

During the 90-day public comment period, a number of entities including academia, commodity groups, federal government, non-governmental organizations, pesticide registrants, industry representatives, resistance action committees, and scientific societies submitted comments to the docket for this PRN (EPA-HQ-OPP-2016-0226) or other dockets listed in Appendix 1. This document first responds to several general comments, followed by comments specific to individual sections or elements listed in the draft of PRN 2017-2. Specific comments on the language and text have been incorporated into the final PRN (i.e., PRN-2017-2) but will not be discussed in this document. Based on the public comments, PRN 2017-2 has been updated as follows:

- (a) the individual resistance management elements have been reorganized into three topic groups rather than individually-numbered elements (i.e., the three topic groups include elements for placement on the label, elements and terms of registration for the registrant, and elements for education, training, and stewardship);
- (b) all herbicides have been placed into a single category (instead of three separate categories of concern);
- (c) OPP eliminated the recommendation that registrants provide a list of weeds resistant to each herbicide product and instead provides a general recommendation that users look to see if there are weeds resistant to the herbicides they are applying in their state or region; and
- (d) OPP clarified the types of pesticides covered by the PRN.

COMMENTERS

The Agency appreciates the many thoughtful comments that were made to the dockets on the management of herbicide resistance. Herbicide resistance management is a complex problem that can only be addressed through cooperation between the many stakeholders – federal agencies, herbicide registrants, academic and extension specialists, crop consultants and advisors, and most importantly, the herbicide user.

Public comments on the Agency’s draft guidance on resistance management were submitted to docket (EPA-HQ-OPP-2016-0226, and to the other dockets listed in Appendix 1). For ease of reference, the Agency has organized the commenters into the following groups. The number in brackets are the document number in docket EPA-HQ-OPP-2016-0226.

Academic / Extension: Bronson, Academic / Extension, University of Tennessee (-0016), Jay McCurdy, Mississippi State University, and Jim Brosnan, University of Tennessee (-0034).

Commodity Groups: California Specialty Crops Council (-0017); National Cotton Council (-0029).

Federal Government: Office of Pest Management Policy, United States Department of Agriculture (-0013); Western Integrated Pest Management Center (-0007).

Non-Governmental Organizations (NGO): Beyond Pesticides (-0006); Center for Food Safety (-0008, -0014).

Pesticide Registrants: Nufarm Americas, Inc. (-0015); DuPont Crop Protection (-0031); Bayer CropScience LP (-0028); FMC Corporation (-0033); Summit Agro USA, LLC (-0027); E. I. DuPont de Nemours and Company (-0012); Syngenta Crop Protection, LLC (-0032); Frank Wong of Bayer Crop Science (-0034); BASF Corporation Crop Protection (-0025); Valent U.S.A. Corporation (-0020); Dow AgroSciences, LLC (-0023).

Pesticide Registrant Organizations: CropLife America (-0010, -0030); RISE, Responsible Industry for a Sound Environment (-0026); Biotechnology Innovation Organization (-0024); Industry Task Force II on 2, 4-D Research Data (-0018).

Resistance Action Committees (Registrant Organizations): North America Fungicide Resistance Action Committee (-0021); US Herbicide Resistance Action Committee (-0005); Insecticide Resistance Action Committee (-0019).

Scientific Societies: American Phytopathological Society (-0022); Weed Science Society of America, Aquatic Plant Management Society, North Central Weed Science Society, Northeastern Weed Science Society, Southern Weed Science Society, and Western Society of Weed Science (-0011; -0035).

COMMENTS RECEIVED AND AGENCY RESPONSE

General Comments and Clarifications

How to Amend Labels: Some herbicide registrants expressed concern about the level of effort needed to amend labels with herbicide resistance management language.

Response: EPA encourages registrants to add the appropriate resistance-management statements through any of the Agency's regulatory mechanisms. In particular, the addition of these statements will be permitted on existing products by (1) notification, (2) amendment or (3) as part of an application for a new product.

Use Sites Covered by this PRN: Several registrants asked about which of the following use sites are covered by this PRN: turfgrass, residential lawns, home gardens, aquatic vegetation, industrial vegetation, forestry, and ornamentals. Registrants also sought clarification if technical and manufacturing products were included.

Response: The Agency used data from Heap (2016) to identify the number of confirmed resistant weed species by use site and ensure that use sites where herbicide-resistant weeds are known to occur are addressed. As is seen in Table 1, most of the use sites identified by the commenters for exclusion have multiple confirmed cases of herbicide resistance. For example, in the United States (U.S.), there are 10 herbicide-resistant weeds found in turfgrass, 8 species in nurseries, 5 species in golf courses, and 2 species in industrial sites.

Table 1. Number of Herbicide-Resistant Weeds in the United States (U.S.) by Crop or Site (Heap, 2016).

Crop or Site	Number of Confirmed Herbicide-Resistant Species in the U.S.
Corn (maize)	51
Soybean	50
Rice	26
Wheat	24
Cotton	18
Roadsides	15
Turfgrass	10
Sorghum	9
Nurseries	8
Orchards	8
Canola	6
Lentils	6
Peas	6
Winter wheat	6
Asparagus	5
Blueberries	5
Chickpea	5
Golf courses	5
Grapes	5
Mint	5
Railways	5
Spring Barley	5

Alfalfa	4
Almonds	4
Carrots	4
Grass seed	4
Onions	4
Sugar beets	4
Tomatoes	4
Seed corn	3
Sugarcane for sugar	3
Vegetables	3
Aquatic	2
Fallow	2
Fence lines	2
Horseradish	2
Industrial sites	2
Pastures	2
Peanut (groundnut)	2
Potatoes	2
Cabbages	1
Kentucky bluegrass	1
Lettuce	1
Pecan	1
Sunflower	1
Sweet corn	1

This PRN communicates the Agency's approach to address herbicide-resistant weeds. It is germane to end-use herbicide products used in agriculture, including commercial turf and sod farms, ornamental production in the open. It also applies to non-agricultural use sites such as golf courses, aquatic vegetation, rights-of-way and vegetation management along roadways. This PRN does not apply to herbicide products labeled for use by the general consumer, such as residential use pesticides. Technical and manufacturing use products are expressly excluded.

Applicability of this PRN to Aquatic Use Sites: The Aquatic Plant Management Society (APMS) provided a link to a white paper (APMS 2014) that highlighted the differences between herbicide resistance management in terrestrial versus aquatic use sites. For example, there are very few cases of herbicide-resistant aquatic weeds, they occur in limited areas, rotation to herbicides with a different MOA is difficult for aquatic managers because there are only a few aquatic herbicides available, and there are a limited number of non-chemical control strategies (e.g., controlling water level or mechanical control).

Response: The Agency agrees that the chemical control of aquatic weeds and the selective pressures for the evolution of herbicide resistance are significantly different from those in terrestrial settings. Current recommendations for aquatic weed control include some measures that both increase and decrease the likelihood of herbicide resistance developing in aquatic weeds. Aquatic ecosystems are a unique and varied use site, and a one-size-fits-all approach to control and resistance management is not feasible. The Agency will continue to work with APMS and aquatic weed specialists to maintain flexibility in regards to herbicide use in aquatic plant control programs and to identify appropriate herbicide resistance best management practices.

Communication, Implementation and Measurement of Success: The weed science societies commented that the Agency should communicate to the agricultural community the expectations for the resistance management plan, how much it will cost to implement, and how the success or failure of this approach will be measured. The United States Department of Agriculture (USDA) Office of Pest Management Policy commented that maintaining local level flexibility and engagement is important and that the herbicide resistance management program undergo periodic review and revision. The Weed Science Society of America (WSSA) and USDA commented that the Agency should explain the expectations of the plan and how the implementation will be measured.

Response: The Agency agrees that communication, rational implementation, and periodic review and revision are critical to the continued success of a resistance management strategy. The Agency intends to work with scientific societies, consultants, registrants, the USDA and other federal agencies, and resistance action committees to communicate the goals and expectations of the herbicide resistance management plan and to determine if revisions are needed. Further, the Agency plans to consult with these entities on whether realistic, implementable, and precise methods/tools are available to measure the success of these measures. The EPA's Office of Inspector General (EPA 2017) has recently reviewed the oversight of herbicide resistance and recommended the Agency work to develop way to measure success.

Enforceability and Voluntary Nature of the PRN: Comments were received concerning the enforceability and voluntary nature of the PRN from multiple registrants, registrant organizations, NGOs, and academic researchers. Further, clarification was sought from the American Phytopathology Society on the specificity of several terms and whether these are

enforceable when placed on pesticide labels.

Response: PRNs are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested parties about important policies, procedures and regulatory decisions. As such, PRNs do not create new legally binding requirements.

The Agency plans to use the herbicide resistance management PRN as the basis to evaluate and implement appropriate actions for individual herbicides as new active ingredients are registered, as old active ingredients are reevaluated in registration review, and when new uses are added to existing registrations.

Pesticide labels contain both enforceable and advisory language. For example, enforceable language would be the maximum application rate for a crop (e.g., *Do not apply more than 1 lb a.i. per acre per year*). Advisory language could include recommendations, not requirements, for scouting (e.g., *Fields should be scouted before application to ensure herbicides and application rates will be appropriate for the crop and weed species present*).

The herbicide resistance management label language is advisory and is intentionally generic because of the diversity of production practices in the United States and to allow the grower flexibility to accommodate local conditions.

Categories of Concern and Categorization of Herbicides: EPA proposed three categories of concern for herbicide resistance development, with the number of management elements increasing with the increasing risk of development of herbicide resistance. The Agency received comments on this proposal from pesticide registrants, registrant organizations, commodity groups, NGOs, USDA, and scientific societies.

There was little support from the commenters for the proposed three categories of concern. Some commenters thought that multiple categories would introduce unnecessary complexity, which could result in user confusion, registrant disputes, and potentially be misleading for co-formulated products containing multiple active ingredients with different Mechanism of Actions (MOA). The USDA and other commenters maintained that measures should be applied to all herbicides to reduce the likelihood for resistance evolving regardless of their resistance potential and that all users of herbicides should be provided with the same educational and training materials regardless of the herbicides being used.

Two alternatives were proposed by commenters. The first alternative does away with the categorization all together and treats all herbicides the same in terms of resistant management. The second alternative is similar, except that in some cases additional resistance management measures may be required for a given herbicide.

Response: The Agency has found the comments against three categories of concern to be compelling and will treat all the herbicides the same, and therefore have a single category. However, in some cases, the Agency may determine that it is necessary to require additional resistant management measures. This single category approach has numerous advantages including the following:

- Provides a consistent approach across all herbicides in order to slow and control the evolution of herbicides resistance regardless of the potential of an individual herbicide to develop herbicide resistance and the current number of herbicide-resistant weeds.
- Provides all herbicides users with educational and training materials, resistance management plans, and other mitigation measures.
- Simplifies the approach and minimizes the number of label changes needed as conditions change.
- Simplifies label language for premix products containing multiple active ingredients with different MOAs.
- Allows for additional resistant management measures to be selectively added when the Agency determines it is necessary.

Applicability to Weeds with Confirmed Resistance: Commenters requested that EPA indicate how it intends to use the proposed 11 elements for herbicides or herbicide groups for which there are already significant numbers or acreage of herbicide-resistant weeds.

Response: As described above, the Agency will treat all herbicides the same in terms of resistant management measures, regardless of whether there are significant numbers of confirmed herbicide-resistant weeds in the U.S.

Categorization of Herbicide Resistance Crops: Several registrants and registrant organizations commented that the herbicide partners of herbicide-resistant crops should not be considered to be of high concern because these active ingredients do not have a higher risk of selecting herbicide-resistant weeds than those active ingredients used on other crops.

Response: The Agency agrees that a given herbicide / weed combination has the same inherent potential for the selection of herbicide-resistant individuals, whether it is an Herbicide Resistant (HR) traited crop or a non-HR crop. The difference lies with the agronomic practices associated with the use of an herbicide partner on an HR traited crop. As has been shown with glyphosate, when several crops, all possessing the same HR trait, are grown in rotation, the diversity of weed control chemicals and practices can be limited resulting in continual selection pressure for herbicide-resistant biotypes. A further concern is that some herbicide-resistant crops (e.g., canola, rice, and sorghum) can outcross with weedy relatives and confer herbicide resistance to populations of those weed species. Since the final PRN will treat all herbicides the same in terms of resistant management, the Agency considers that this is no longer an issue.

Comments on Individual Resistance Management Elements

Draft Element 1. List Mechanism of Action (MOA) Group Number on label.

Comments: The Agency received comments from multiple registrants, resistance action committees, commodity groups, and scientific societies. All commenters, including the USDA, supported the placement of the MOA on the label. Some commenters questioned which

classification system should be used. One system, used by the Herbicide Resistance Action Committee (HRAC) uses an alphabetic system to group herbicide active ingredients. The Weed Science Society of America (WSSA) uses a numeric system for MOA groups. The website, <http://hrac.tsstaging.com/tools/classification-lookup>, may be used to translate between the two systems. Some commenters asked for clarification about reporting the MOA on the label when the product contains multiple herbicides in more than one MOA group.

Response: The Agency will retain this element in the PRN. There was strong support across all stakeholder groups for including the MOA Group Number on the herbicide label. Herbicide labels in the U.S. currently displaying the MOA group use the WSSA numeric groups. The Agency prefers the continued use of WSSA numeric groups to denote the MOA.

Clarification about listing the MOA on the label if the product contains multiple active ingredients are addressed in PRN 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*.

Final PRN: Place the MOA, using the WSSA Groupings (as described in PRN 2017-1), on the label.

Draft Element 2. List seasonal and annual maximum number of applications and amounts.

Comments: The Agency received comments from multiple registrants, resistance action committees, and commodity groups supportive of the requirement to list the seasonal and annual maximum number of applications and amounts of active ingredient on the label. Some groups were concerned that this was an attempt by the Agency to reduce application rates.

Response: The Agency will retain this element in the PRN. Most commenters agreed that both the seasonal and annual maximum number of applications should appear on the label. This label information will allow growers and crop consultants to design an herbicide resistance management plan that takes into account the maximum amount of an herbicide allowed to be applied in a season or year. The intent of this element is to provide clarity and information for planning purposes and not to reduce application rates as some comments suggested. Maximum rates and number of applications of a pesticide forms the basis for the Agency risk assessments for human health and the environmental effects, but has not always been completely and clearly described on the label.

Final PRN: Clearly express all currently required application parameters and product information on the label, including: maximum dose per application, maximum dose per crop cycle or per year, maximum number of applications per crop cycle or per year. Example label statement are provided in the PRN.

Draft Element 3. Provide Resistance Management language from PR Notice 2016-X, and/or Best Management Practices (BMP) language from Weed Science Society of America (WSSA) &

Herbicide Resistance Action Committee (HRAC), and/or HRAC proposed guidelines for herbicide labels. Note that BMPs should be appropriate to crop and production system.

Comments: EPA received comments from several groups both for and against this element. The groups supporting this information, including the USDA, thought it could be a valuable tool for users and crop consultants and many registrants already place this type of information on their labels. Other groups felt that labels were already too long, that the information would be confusing, or might not be locally relevant. Some commenters said that labels are not the best place for this information and that adding resistance management language would not be effective. Some commenters said that a website might be more effective place for the information while other comments said that users would not look at a website. Some comments said that there could be substantial work in amending their labels to include this information.

Response: The Agency will retain and modify this element so that information on BMPs is available in a condensed form on the label. The Agency considers this to be the most expedient and direct method of providing the information to herbicide users. The Agency has determined that adding this general language to the label will not be an excessive burden on the registrants because it could occur during normal label changes and would not require regular updating.

Final PRN: Label statements describing best management practices for resistance management based on PRN 2017-1. Best Management Practices from WSSA, and the HRAC proposed guidance. Example label statements are provided in the PRN.

Draft Element 4. Instruction to users to scout before and after application.

Comments: The Agency received comments from several groups, including the USDA, that were supportive of this element. However, some groups did not support the idea for specific use sites because they said the users did not have the resources to properly scout the sites (e.g., turf, ornamentals, vegetation management, forestry, or aquatic systems). Two groups recommended that historic information on pest pressure could be used in conjunction with scouting to help inform decisions (e.g., historic information could be used to recommend a pre-emergence herbicide application). Several groups requested that the Agency clarify that scouting is a recommendation and not a requirement.

Response: The Agency will retain this element in the PRN. This label language will remind users and crop consultants to scout before and after an herbicide is applied. The suggested language is not a requirement but rather a reminder to users and crop consultants that scouting is an important tool for control of herbicide-resistant weed species.

Final PRN: Recommendations (not requirement) that the field should be scouted both before and after a pesticide application (as described in PRN 2017-1). Example label statement is provided in the PRN.

Draft Element 5. Provide definition of Likely Resistance on label.

Comments: EPA received comments both for and against defining resistance on herbicide labels. Commenters, including the USDA, recommended that the Agency use the term “suspected” resistance as originally described by the WSSA instead of “likely” resistance. Some commenters thought the definition should be provided on a website instead of the label. Some comments said that providing the definition could lead to the reporting of likely resistance in weed species in error.

Response: The Agency will retain this element in the PRN, but will use the term “suspected” resistance instead of “likely” resistance. The Agency recommends placing the definition of suspected resistance on the labels to increase awareness among users and their representatives to help identify suspected herbicide-resistant weeds and proactively take action before they become widespread in their fields. The Agency recommends that the definitions be placed on labels because this is the most expedient and direct method of providing the information to herbicide users. The Agency thinks there will be very few cases of inaccurate reporting because the definition of suspected resistance from the WSSA (listed below) easily rules out equipment and application problems and registrants, their representatives, or possibly extension agents will likely be contacted to review the situation before it is reported to anyone else.

Final PRN: A statement defining suspected resistance should be placed on the label, as follows:

Suspected herbicide-resistant weeds may be identified by these indicators (Norsworthy et al. 2012, 0.39).

- Failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds;
- A spreading patch of non-controlled plants of a particular weed species; and
- Surviving plants mixed with controlled individuals of the same species.

Draft Element 6. Instruction to user to report lack of performance to registrant or their representative.

Comments: The Agency received many comments in support of this element, including the USDA, and the potential to help find and identify “suspected” resistant weeds before that biotype can become established in a field. Commenters recommended that these reports be available to crop advisors, weed scientists, and others in the industry to help develop an effective early warning system. Some commenters have stated that this element should apply to all registrants including those whose business models do not include performance guarantees or field staff. Some comments from registrants did not support this element because they do not have the technical expertise or resources to address each occurrence of lack of performance.

Response: The Agency will retain this element in the PRN. The Agency recommends that users report lack of performance to the registrant of that herbicide. For many users and consultants reporting lack of performance is already a normal practice and considered an intrinsic part of their business process. Reporting lack of performance will allow the registrant or its

representative to identify suspected herbicide-resistant weeds and suggest methods to proactively take action before these biotypes become widespread in their fields.

Final PRN: Label statement that the grower should report lack of performance to the registrant or their representative and proactively take action before escaped weeds become widespread in their fields. Example label statements are provided in the PRN.

Draft Element 7. List confirmed resistant weeds in a separate table and list recommended rates for these weeds with the table.

Comments: The Agency received many comments on this proposed element. In general, commenters agreed that information about the confirmed resistant weed species and the methods of control would be useful to the growers. However, there was little support for placement of this information on the product label. Major objections included: the burden associated with multiple label updates as new resistant species evolved, more complicated labels, and that listing multiple rates on a label for different weed species could be confusing to users. Commenters suggested that this information may be better suited for a website, with a link on the label.

Response: The Agency will modify this element in the PRN. EPA acknowledges that creating this type of table would require a great deal of effort, could list numerous weed species, and could require multiple updates over time. The Agency will recommend that an advisory statement (as provided in the PRN) be placed with the list of target pests rather than a separate table listing herbicide-resistant weeds.

Final PRN: Label statements on local resistant weeds. Example label statements are provided in the PRN.

Draft Element 8. Registrant report new cases of suspected and confirmed resistance to EPA and users yearly. This is in addition to any adverse effects reporting currently required under FIFRA Section 6 (a)(2).

Comments: The Agency received comments both for and against this element to report suspected and confirmed resistant weed species to the Office of Pesticide Programs. Some commenters thought that this would help provide users with early warning of herbicide-resistant weed species. The USDA said the Agency, in partnership with registrants, should determine the limits on reporting. The criteria for deciding when sufficient cases of suspected resistance have been reported and further reports are no longer needed. Some commenters oppose reporting new cases because the current 6(a)(2) reporting system is effective and additional reporting is viewed as overly burdensome. Others oppose additional reporting because they believe that once an herbicide-resistant weed is reported anywhere in the U.S. further reporting is not needed. Also, some commenters stated that this reporting element should apply to all registrants, including those who do not have field staff, to ensure that all registrants participate equally in this type of reporting. Commenters requested clarification as to whether reporting of suspected resistance would require resistance testing and noted that resistance testing could be costly. Some

commenters incorrectly thought that reporting of suspected and confirmed resistance would be a label requirement.

Response: The Agency will retain this element in the PRN. Registrants should report suspected and confirmed resistance to the Agency and should make it publicly available in order to raise awareness of developing problems and to enable crop consultants and users to proactively take action before herbicide-resistant biotypes become widespread in their fields. The Agency plans to work with the USDA and registrants to clarify the limits on reporting of confirmed herbicide-resistant weeds. The EPA's Office of Pesticide Programs, Information Technology and Resources Management Division (OPP/ITRMD) receives and tracks reports of adverse environmental impacts and herbicide-resistant weeds in the 6(a)(2) adverse incident database (and in the a 6(a)(2) Letters and Studies database) from August 5, 1988 to the present. Because registrants are already required to report adverse environmental impacts and herbicide-resistant weeds, the Agency does not anticipate there will significant additional costs involved in implementing this element.

The Agency is also aware that there is low compliance with the reporting requirements under FIFRA Section 6 (a)(2). The Agency compared the number of reports of unique cases of herbicide-resistant weeds submitted under 6(a)(2) adverse effects reporting requirement to the number of unique cases reported in the International Survey of Herbicide Resistant Weeds (Heap, 2016), and found that only 10 percent of the cases had been reported.

Final PRN: Registrant(s) to report new cases of suspected and confirmed resistance to EPA and users.

Draft Element 9. Provide growers with (a) Resistance Management Plan, (b) Remedial Action Plan (to control resistant weeds this season or next season) and (c) Educational materials on resistance management. Plans should be locally developed and easily modified. EPA recommends that registrants work with Extension, Consultants, Crop Groups, HRAC, & USDA.

Comments: The Agency received many comments supportive of this recommended goal. Some comments suggested that the Agency should work with commodity, industry and state university extension groups to improve resistance management plans and that these plans would be a logical extension of existing IPM (Integrated Pest Management), stewardship and training programs already in use for many crops. The WSSA requested further clarification of the plan (e.g., definitions for what is included in a plan, what entities are responsible for implementing the plan, what "locally" means). Also, the WSSA recommended 10 items for inclusion in a resistance management plan and made several recommendations for items to include in a remedial plan. Some commenters recommended that this information be made available on a website. The USDA agreed with this element and stressed that the plans should address local conditions.

Some commenters oppose this element saying it is too broad, would be a large resource drain, and needs further clarification on some of the terms (e.g., "locally produced" and specifying the

elements of a resistance plan). Some commenters mistakenly thought that this would be information on a label.

Response: The Agency will retain this element in the PRN. The Agency has discussed these plans and educational materials with the HRAC, USDA, and WSSA and will continue to work with commodity, industry, and state university extension groups to discuss way to provide resistance management plans, remedial action plans, and educational materials to users. These plans would be a logical extension to the existing IPM, stewardship, and training plans already in place for many crops. The Agency has included, as an appendix to the PRN, the items that the WSSA recommended be part of a resistance management plan.

Final PRN: Provide educational and training materials for growers and users. These should include a resistance management plan, a remedial action plan (to control resistant weeds this season or next season), and educational materials on resistance management. Plans should be locally developed and easily modified. EPA recommends that registrants work with Extension, Consultants, Crop Groups, HRAC, and the USDA.

Draft Element 10. For combination products with multiple MOAs, list which herbicide is controlling which weed (a 3-way mixture may only have one effective MOA for some problem weeds). List minimum recommended rate if resistance is suspected.

Comments: There were a number of comments for and against this element. In general, commenters agreed that information about the confirmed resistant weed species and the information on the number of effective MOAs for each weed species would be useful to the growers. However, there was little support for placing this information on the product label. Some commenters objected because of the difficulty in collecting the information, the complexity of the table required to show the information, the differences in regional sensitivity of weeds, and the work involved in keeping the information current.

Response: There are over 33 different weed species in the United States with confirmed resistance to more than one MOA as of November, 2016 (Heap, 2016), which demonstrates how difficult it can be for an individual user to determine if a given mixture will be effective on their use site. However, the Agency does acknowledge that creating and maintaining a table with this information would require a great deal of effort and the information necessary to fill out the table is not always readily available. The Agency will modify this element in the PRN and will provide advisory label statements in place of this element.

In addition to advisory language, the Agency will work with the WSSA and HRAC to explore other approaches for making this type of information available to users and crop consultants.

Final PRN: Label statements on local resistant weeds. Example label statements are provided in the PRN.

Draft Element 11. Any additional specific requirements (e.g. mandatory crop rotation, unique agronomic aspects, additional training, time limited registration, etc.).

Comments: There were a number of comments for and against this element. Several commenters support this element and agree there may be other measures that could be effective in reducing the selective pressure for the evolution of resistance. Other commenters requested that any specific requirements should apply equally to all registrants and that the Agency should consider standardizing those requirements across all registrations of similar products. Some commenters oppose this element saying it is not needed or it could create uncertainty for registrants because it is open-ended. The USDA recommended that the Agency consider the impact on growers of any additional requirements.

Response: The Agency will retain this element because it may be helpful in reducing the selective pressure for the evolution of herbicide-resistant weeds. However, this element would be implemented on a limited basis for unique situations. Such a case might occur where an herbicide-resistant crop has a weedy relative and use of the herbicide could accelerate evolution of resistance in the weedy relative. In this situation it may be appropriate to place other conditions on the registration (e.g., apply only with another MOA, apply every other year, statements about pollen flow for herbicide resistant crops with weedy relatives, or concern about non-target site resistance).

Final PRN: Unique terms and conditions of registration may be required on a case-by-case basis.

Comments on the PRN 2016-XX Appendices

APPENDIX I. Herbicide Mechanisms of Action (MOA) and the Agency's Level of Concern for Herbicide Resistance

Comments: See comment section related to Categories of Concern and Categorization of Herbicides.

Response: As discussed in Categories of Concern and Categorization of Herbicides section, the Agency will treat all herbicides the same and has removed the appendix.

APPENDIX III. Best Management Practices for Herbicide-Resistant Weeds

Comments: The Agency received comments supportive of the inclusion of the Best Management Practices (BMP) on the label. However, one commenter suggested that the list was too long and could be shortened.

Response: The Agency has condensed the text of the herbicide resistance BMPs and recommends that the label only include BMPs that are appropriate for the labeled use sites.

REFERENCES

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APPENDIX 1. Dockets for Pesticide Registration Notices and Proposed Interim Decisions

Draft Guidance: Pesticides; Pesticide Registrants on Pesticide Resistance Management Labeling (PRN): EPA-HQ-OPP-2016-0242

Registration Review Proposed Interim Decision: Sodium Acifluorfen: EPA-HQ-OPP-2010-0135

Registration Review Proposed Interim Decision: Propoxycarbazone: EPA-HQ-OPP-2015-0095

Registration Review Proposed Interim Decision: Bentazon: EPA-HQ-OPP-2010-0117; Comment also submitted under HRAC, 08-01-2016 (HRAC, 0005)

Proposed Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean: EPA-HQ-OPP-2016-0187; Comment also submitted under HRAC 08-01-2016 (HRAC, 0005)

Proposed Interim Registration Review Decision for Sulfonylurea Herbicides (as a Group): EPA-HQ-OPP-2015-0774

Proposed Interim Registration Review Decision for Bensulfuron-methyl: EPA-HQ-OPP-2011-0663

Proposed Interim Registration Review Decision for Chlorimuron-ethyl: EPA-HQ-OPP-2010-0478

Proposed Interim Registration Review Decision for Chlorsulfuron: EPA-HQ-OPP-2012-0878

Proposed Interim Registration Review Decision for Flazasulfuron: EPA-HQ-OPP-2011-0994

Proposed Interim Registration Review Decision for Foramsulfuron: EPA-HQ-OPP-2012-0387

Proposed Interim Registration Review Decision for Halosulfuron-methyl: EPA-HQ-OPP-2011-0745

Proposed Interim Registration Review Decision for Imazosulfuron: EPA-HQ-OPP-2015-0625

Proposed Interim Registration Review Decision for Iodosulfuron-methyl-sodium: EPA-HQ-OPP-2012-0717

Proposed Interim Registration Review Decision for Mesosulfuron-methyl: EPA-HQ-OPP-2012-0833

Proposed Interim Registration Review Decision for Metsulfuron-methyl: EPA-HQ-OPP-2011-0375

Proposed Interim Registration Review Decision for Nicosulfuron: EPA-HQ-OPP-2012-0372

Proposed Interim Registration Review Decision for Orthosulfamuron: EPA-HQ-OPP-2011-0438

Proposed Interim Registration Review Decision for Primisulfuron-methyl: EPA-HQ-OPP-2011-0844

Proposed Interim Registration Review Decision for Prosulfuron: EPA-HQ-OPP-2011-1010

Proposed Interim Registration Review Decision for Rimsulfuron: EPA-HQ-OPP-2012-0178

Proposed Interim Registration Review Decision for Sulfometuron-methyl: EPA-HQ-OPP-2012-0433

Proposed Interim Registration Review Decision for Sulfosulfuron: EPA-HQ-OPP-2011-0434

Proposed Interim Registration Review Decision for Thifensulfuron-methyl: EPA-HQ-OPP-2011-0171

Proposed Interim Registration Review Decision for Triasulfuron: EPA-HQ-OPP-2012-0115

Proposed Interim Registration Review Decision for Tribenuron-methyl: EPA-HQ-OPP-2010-0626

Proposed Interim Registration Review Decision for Trifloxysulfuron-Sodium: EPA-HQ-OPP-2013-0409

Proposed Interim Registration Review Decision for Triflusulfuron-methyl: EPA-HQ-OPP-2012-0605